



## Clintrial™

### Clintrial™ Capabilities:

- Streamlines multilingual paper-based direct data entry
- Provides global standardization with maximum flexibility
- Increases real-time access to clinical data
- Enhances clinical research data quality

### Key Features:

- Production-proven clinical data management
- CDISC support
- Extensive coding and reporting features
- Regulatory compliance
- Low total cost of ownership

[www.phaseforward.com](http://www.phaseforward.com)

## Reduce Time and Costs Associated with Clinical Trials

### The Phase Forward Advantage

With 40% of pharmaceutical companies' R&D budgets spent on the clinical development process, shrinking the time to a new drug application (NDA) submission is a business imperative. For more than a decade, the Clintrial solution has been the clinical data management system (CDMS) for more NDAs than any other commercial CDMS. 11 of the top 15 pharmaceutical companies rely on the Clintrial solution to help them more efficiently manage their clinical trial data.

Standing behind Clintrial's proven CDMS product technology is the clinical experience and expertise of Phase Forward. No other vendor can offer the breadth of clinical, safety, regulatory, and technology expertise, or the depth of real-world clinical trials experience that Phase Forward does. Our customer services organization delivers results-oriented, global support services on a multilingual basis to our customers 24 hours a day, 7 days a week. Today, more than 200 Clintrial customers count on the accumulated knowledge of Phase Forward to meet their clinical data systems' requirements.

### Grow with a Production-Proven Architecture

The Clintrial architecture provides for both configurability and scalability. Modular functionality provides flexible purchasing and deployment options. The Clintrial system can be installed, set up, and begin running in a matter of days without any custom development required, which is substantially less time than competitive offerings. The system is also easier to manage and maintain, further reducing the need for extensive consulting services and support that often accompany other CDMS systems.

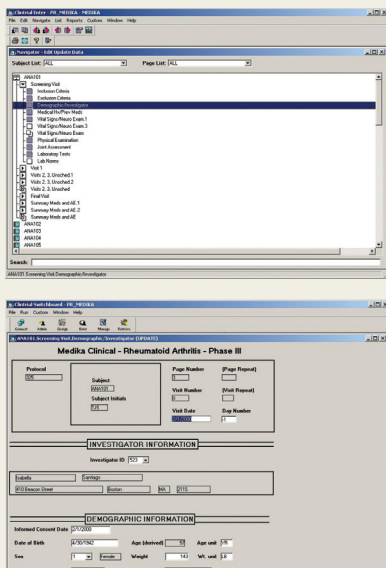
As your needs expand, you can add additional functionality knowing that the Clintrial system will grow with you. No other data management system scales as well to meet the rigorous demands of large pharmaceutical companies. Production-proven in over 4,000 clinical trials, Clintrial is recognized as the standard industry benchmark.

### Streamlined Study Set-Up and Design

*The Clintrial solution provides unique functionality for efficiently initiating and designing a trial study:*

- Set up study default parameters for database, protocols, users, access rights, and user groups without requiring Oracle database expertise
- Create data entry screens quickly and easily from a Graphical User Interface (GUI) with no manual programming involved
- Generate complete study metadata reports (including item definition, edit check logic, and data entry screens) to assist in system validation; and audit metadata changes

Flexible standardization capabilities also set the Clintrial system apart. Study definitions are standardized through a multi-tier global library that supports many different levels of standards. Reusability is available at all levels from a single data item to a complete study database. Enforcement options can be set at varying levels, from copied object lockdown to complete freedom to change the attributes and composition of copied objects. Flexible standardization enables you to maintain essential data consistency across different studies, facilitating data pooling and analysis, while still supporting the varying requirements of individual clinical research studies.



**Intuitive data entry screens**

Clintrial's GUI has been designed to mirror the way that clinical personnel interact and work with paper-based clinical data. As a result, Clintrial data entry screens are more intuitive and familiar, and therefore easier to use.

**System Requirements:**

- Please visit [www.phaseforward.com/products](http://www.phaseforward.com/products)

**Intuitive Direct Data Entry**

Clintrial's GUI has been designed to mirror the way that clinical personnel interact and work with paper-based clinical data. As a result, Clintrial data entry screens are more intuitive and familiar, and therefore easier to use. Intelligent navigation features aid in the rapid, direct data entry of paper-based case report forms (CRFs) in single entry, interactive double entry, or blinded double entry mode.

**Comprehensive Data Management**

*At the heart of the Clintrial system is a full range of proven, centralized clinical data management capabilities:*

- Validation (edit checks) run on demand or scheduled
- Integrated data discrepancy management and resolution
- Batch data loading and screening
- Powerful configurable auto-encoding engine to code adverse events, diseases or drugs to your choice of dictionary
- Full MedDRA dictionary support
- Global change and delete functionality
- Comprehensive thesaurus management functionality
- Central laboratory data loading and processing
- Comprehensive security administration
- Configurable audit trails

**Flexible Data Retrieval and Reporting**

Data can be easily extracted from the Clintrial database without requiring SQL or database training. Flexible reporting capabilities let you target and report relevant information quickly and easily through either a point-and-click, ad hoc query tool, forms-based query options, or by direct SQL. You can save queries within a query library, enabling reuse and sharing. Data retrieved from the Clintrial system can be saved in a variety of formats including SAS, Excel, and delimited ASCII files.

**Global Data and Metadata Distribution**

To support the expansion of multinational clinical trials, the Clintrial system provides optional multi-site functionality to distribute trial data and metadata among multiple sites using a local or wide area network. Clintrial's GUI is available in both English and Japanese, and can support studies with a multitude of different languages. The system controls and tracks the distribution of trial metadata and the scheduled or on-demand replication of data between separate databases on a network. This allows different locations to share data and participate in the same study, even though each may have their own database installation.

**Integrating the Industry's Leading Clinical Management Solutions**

*Phase Forward is the only clinical trial systems vendor that can integrate the market-leading EDC, CDMS, and Safety systems:*

- Our Clintrial Integration Solution (CIS) allows you to expand your existing clinical trial process to leverage electronic data capture (EDC) by integrating the InForm™ software, the premier EDC system, with Clintrial. With CIS, you can support either paper data capture, electronic data capture, or both within a single trial, combining the benefits of both products into a single system for data entry and cleaning, query processing, data management and reporting, and study archiving.
- The Clintrial system can transfer drug safety information to Phase Forward's industry-leading Empirica™ Trace adverse events management system to uncover the emerging safety profile of a product under development.
- Clintrial also integrates with Phase Forward's Central Coding application for all multilingual coding needs.

**Regulatory Compliance**

The Clintrial system has been designed to enable our customers to deploy it as part of a validated system compliant with GCP predicate rule requirements, laws, and regulations applicable to the conduct of clinical trials, and FDA 21 CFR 11 pertaining to the use of electronic records and signatures.

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